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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,723

02/23/2004

Gregory G. Bojrab

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ICE MILLER LLP  
ONE AMERICAN SQUARE, SUITE 3100  
INDIANAPOLIS, IN 46282-0200

EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/784,723	<b>Applicant(s)</b> BOJRAB, GREGORY G.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                                    |

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### DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

The status of the parent case(s) should be updated.

In keeping with scientific custom, the names of genera and species of microorganisms should be capitalized and underlined or italicized throughout the specification and claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No.

6,696,057 and claims 1-3 of U.S. Patent No. 6,641,808. Although the conflicting claims are not identical, they are not patentably distinct from each other because the applicant and the patents are directed to the same probiotic compositions comprising a mixture of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* and a carbohydrate medium suitable for the treatment of mammals.

Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/699938. Although the conflicting claims are not identical, they are not patentably distinct from each other because Although the conflicting claims are not identical, they are not patentably distinct from each other because the applications are directed to the same probiotic

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compositions comprising a mixture of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* and a carbohydrate medium suitable for the treatment of mammals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over van der Schaft taken with Sozzi *et al.*, Kondratenko *et al.* and Cavaliere Vesely *et al.*, of record.

The claims are directed to a concentrated and lyophilized probiotic composition comprising a mixture of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* and a carbohydrate medium suitable for administration to a subject.

The van der Schaft reference discloses a probiotic composition such as a dairy product, comprising a mixture of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* and a carbohydrate medium, inherently suitable for the treatment of obesity, which is concentrated at least to some extent and which is lyophilized. See, e.g., van der Schaft, Examples 1 and 2.

In addition each of Sozzi *et al.* and Kondratenko *et al.* discloses a probiotic composition such as a dairy product, comprising a mixture of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* and a carbohydrate medium, suitable for the treatment of obesity, col. 2, lines 42-56; Kondratenko *et al.*, col. 9, lines 50 et seq.;

The references differ from the claimed invention in the use of a lyophilized product packaged in capsules, tablets or caplets. However, Cavaliere Vesely *et al.* discloses the use of preparations of *Lactobacillus* and *Streptococcus* for similar applications which are dispensed in various combinations and in the form of tablets, capsules, packets, etc. (See, e.g., col. 2, lines 30 to col. 3, line 50.).

Regarding the required ratios, one of ordinary skill in the art would have known to adjust the ratios of microorganisms in the compositions in view of the ranges and ratios suggested by

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the teachings of Cavaliere Vesely *et al.* of 5-90% *Lactobacillus* and 10-95% *Streptococcus*, for example. In addition, the reference teaches that the compositions may contain  $2 \times 10^{13}$  bacteria.

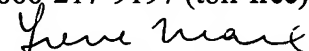
Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of van der Schaft, or Sozzi *et al.* or Kondratenko *et al.* by dispensing the lyophilized and concentrated microorganisms in the form of tablets, capsules or packets, and in an approximate ratio of 2:1 to 9:1 as suggested by Cavaliere Vesely *et al.* for the expected benefit of obtaining a viable and stable probiotic composition suitable for the treatment of obesity because of the properties of dairy products, and yogurt, in particular, as a filling and healthy foods suitable for a slimming regimen, particularly if low fat.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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